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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/871,723	06/04/2001	Ryuji Takahashi	Q63839	1424	
7	7590 07/22/2003				
SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC 2100 Pennsylvania Avenue, N.W. Washington, DC 20037-3213			EXAM	EXAMINER	
			WILSON, D	WILSON, DONALD R	
			ART UNIT	PAPER NUMBER	
			1713	X	
·			DATE MAILED: 07/22/2003	DATE MAILED: 07/22/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

•			# <del>98</del>				
		Applicati n No.	Applicant(s)				
Office Action Summary		09/871,723	TAKAHASHI ET AL.				
		Examin r	Art Unit				
		Donald R Wilson	1713				
Th MAILING DATE of this communication appears on the cover sheld with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status							
1)⊠	Responsive to communication(s) filed on 10 J	<u>luly 2003</u> .					
2a) <u></u>	This action is <b>FINAL</b> . 2b)⊠ Th	is action is non-final.					
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4)⊠ Claim(s) 2-7,9-13 and 15-23 is/are pending in the application.							
4a) Of the above claim(s) 15 and 20-23 is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠	6)⊠ Claim(s) <u>2-7,9-13 and 16-19</u> is/are rejected.						
7)	Claim(s) is/are objected to.						
8)	Claim(s) are subject to restriction and/o	r election requirement.					
Application Papers							
9)☐ The specification is objected to by the Examiner.							
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
_	Applicant may not request that any objection to the	· ·					
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
2) D Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) 🔲 Notice of Inform	ary (PTO-413) Paper No(s) al Patent Application (PTO-152)				

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#### **DETAILED ACTION**

### Allowability of Claims/Final Rejection Withdrawn

- 1. The indicated allowability of Claims 2-7, 9-13 and 15-23 are withdrawn in view of the newly discovered reference(s). Rejections based on the newly cited reference(s) follow. Additionally a new rejection under 35 U.S.C. § 112, second paragraph, of Claims 4-5 is applied.
- 2. In view of the newly cited art the finality of the previous Office Action is withdrawn. The withdrawal of Claims 15 and 20-23 as being drawn to a non-elected invention due to the restriction requirement, is reinstated. These claims were non-elected without traverse in Paper No. 4. Should the remaining claims again be found allowable the Examiner will again consider rejoining the restricted claims, providing they have all the limitations of any allowed claims.

#### Response to Amendment

Applicant's amendment filed 7/10/03 has been entered, and the rejection of Claim 14 under 35
 U.S.C. § 112, second paragraph, has been withdrawn.

## Previously Cited Statutes

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### Claim Rejections - 35 USC § 112, Second Paragraph

5. Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2, from which the claims depend, provides no antecedent basis for "the hydrophilic monomer (B)" being other than a (meth)acrylic acid ester of a polyhydric alcohol. This rejection could be overcome by amending Claim 3 to recite "further contains" as opposed to "contains". Should applicant argue for patentability wherein the N-vinylcarboxylic acid amide monomer is the sole hydrophilic monomer, the claim would be rejected under 35 U.S.C. § 112, first paragraph, as being non-enabled as it isn't seen that there is any teaching in the specification as to how to chemically modify such a polymer to make an ion-exchange polymer.

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#### Claim Rejections - 35 USC § 102(b)/§ 103(a)

- 6. Claims 2, 4, 6, 9-13, 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Strop'018 or Strop'461.
- 7. Strop'018 discloses and claims hydrophilic ion-exchange resins prepared by copolymerizing hydroxyalkyl (meth)acrylates and (meth)acrylamides with a cross-linking agent, among which divinylbenzene is specifically claimed. The hydroxyl groups in the resulting polymer are chemically modified in order to introduce anionogenic groups (e.g., Claims 1-2). Chemical modification by reaction with chlorosulfonic acid or a chloroethylsulfonic acid to introduce a sulfo group is demonstrated by at least Examples 7, 11, 22, 30 and 42, and would have been readily envisaged wherein the cross-linking agent was divinyl benzene. The use of the copolymer gel in chromatographic separations by passing a liquid preparation in contact with the ion exchanger is specifically taught (e.g., Claim 11). Packing of a material in a column for this purpose would have been readily envisaged by one of ordinary skill in the art, and further is exemplified in Example 45. In as much as the exemplified dried polymers have exchange capacities of ranging from at least about 1 to 3.5 meq/g, it would be inherent that the copolymers contain at least 10 wt.% of the hydroxyl group containing monomer (B).
- 8. Strop'461 also discloses and claims hydrophilic ion-exchange resins prepared by copolymerizing hydroxyalkyl (meth)acrylates and (meth)acrylamides with a cross-linking agent, among which divinylbenzene is specifically claimed. The hydroxyl groups in the resulting polymer are chemically modified in order to introduce cationic groups (e.g., Claims 1-2). An example of a hydroxypropyl methacrylate/divinylbenzene modified with a bromoethyltrimethylammonium compound is given in Example 24. The chemical modification by the introduction of quaternary ammonium groups is also exemplified by reaction with epichlorohydrin followed by subsequent reaction with trialkanol amines (Examples 2-5), and would have been readily envisaged wherein the cross-linking agent was divinyl benzene. Another alternative is the reaction of the hydroxyl groups with an epoxyammonium compound such as N-(2,3-epoxypropyl)-N,N,N-triethylammonium chloride (the reaction product of triethylamine and epichlorohydrin) as exemplified in Examples 22 and 23. Use of the copolymer gel as a packing material in a column for chromatographic separations is either clearly taught or readily envisaged by one of

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ordinary skill in the art from the teachings at col. 2, lines 34-46. In as much as the exemplified dried polymers have exchange capacities of ranging from at least about 0.6 to 1.6 meq/g, it would be inherent that the copolymers contain at least 10 wt.% of the hydroxyl group containing monomer (B).

- 9. Claims 2-3, 6, 9-13, 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hradil.
- hydroxyalkyl (meth)acrylates with a cross-linking agent, among which divinylbenzene is specifically claimed (Claim 1). The hydroxyl groups in the resulting polymer are chemically modified by esterification with sulfuric acid, chlorosulfonic acid, sulfur trioxide (which introduce sulfo groups), or metaphosphoric acid (Claim 1, col. 1, lines 43-53). All of the examples of cross-linked hydroxyalkyl methacrylate copolymers contain more than 30 wt.% of polymerized ethylene dimethacrylate as the cross-linking agent. Thus, one of ordinary skill in the art would have envisaged using similar amounts of divinyl benzene as the cross-linking agent as the cross-linking agents are taught to be equivalent. Amounts of the hydroxyl alkyl (meth)acrylates employed in all of the examples are at least 10 wt.% or more, making such amounts readily envisaged, and the equivalents of the covalently bonded ionic groups would clearly meet the limitations of the instant claims. Use of the crosslinked copolymer as a packing material in a column for chromatographic separations is either clearly taught or readily envisaged by one of ordinary skill in the art from the teachings at col. 2, line 53 to col. 3, line 2.
- 11. Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over (i)

  Strop'018 or Strop'461 as applied to Claims 2, 4, 6, 9-13, 16 and 18 above, or (ii) Hradil as applied to Claims 2-3, 6, 9-13, 16 and 18, and each further in view of Lee.
- 12. The Strop and Hradil references discussed above are deficient in not disclosing cartridges packed with the ion exchange materials. However, such is well known in applications using ion exchange materials for instance as is disclosed by Lee. As discussed in the Office Action of 2/19/03, Lee discloses ion exchange polymers containing both a hydrophobic group (e.g., DVB) and an ion exchange group (e.g., a sulfonate group or a quaternary ammonium group), as for example are exemplified in Examples 2 and 6. The use of columns and cartridges containing particles of the ion exchange resin are also

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disclosed (e.g., col. 10, line 46 to col. 11, line 16). It would have been obvious to one of ordinary skill in the art to use either cartridges or columns to contain the ion exchange particles of Strop'018, Strop'461 or Hradil in ion exchange processes because such is well known and practiced in the art as for instance is taught by Lee. As to any further limitations of Claims 16-19, these are seen as intended uses which do not impart patentability to the claimed subject matter.

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strop 018 or 461 as applied to Claims 2, 4, 6, 9-13, 16 and 18 above, and further in view of Hradil.

14. The Strop references discussed above are deficient in not disclosing the amount of cross-linking agent to employ. However, as disclosed by Hradil it is well known to use levels of cross-linking agent ion ion-exchange particles in an amount of 30 wt.% or more. Lacking a showing of criticality for specific levels it would have been obvious to one of ordinary skill in the art to use levels of divinyl benzene in an amount of 30 wt.% or more as the cross-linking agent in the copolymer gels taught either of the Strop references because such levels are will known in the art in the preparation of ion-exchange materials.

# Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donald R Wilson whose telephone number is 703-308-2398.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 703-308-2450. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications. The unofficial direct fax phone number to the Examiner's desk is 703-872-9029.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-2351.

Donald R Wilson Primary Examiner Art Unit 1713

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